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**A prospective, controlled clinical trial evaluating the clinical radiological and  
aesthetic outcome after 5 years of immediately placed implants in sockets  
exhibiting periapical pathology**

Jung, Ronald E ; Zaugg, Balthasar ; Philipp, Alexander O H ; Truninger, Thomas C ; Siegenthaler, David W ;  
Hämmerle, Christoph H F

**Abstract:** **OBJECTIVE:** The aim was to compare the clinical, aesthetic and radiological outcome of immediately placed implants in sockets with or without periapical pathology 5 years after placement. **MATERIALS AND METHODS:** Twenty-seven patients were followed 5 years after immediate implant placement (test-group: 12 patients with periapical pathologies; control-group: 15 patients without periapical pathology). Clinical (FMBS, FMPS, CAL, keratinized mucosa), aesthetical (length of clinical crown, Papilla index), and radiological (vertical distance implant shoulder to first bone to implant contact (IS-BIC)) parameters were assessed. Both 95% confidence intervals, as well as results of statistical tests (one-sample, two-sample, paired t-test) were provided. **RESULTS:** After 5 years the implant survival rate was 100% for all 27 implants. In the test group the width of the keratinized mucosa increased significantly over the observation period ( $0.8 \pm 1.0$  mm). Concerning aesthetic parameters at the 3-month as well as at the 5-year examination no statistically significant difference could be found between the two groups. In the control-group the papilla mesial and distal to the implant increased statistically significant during the observation period by  $0.5 \pm 0.5$  and  $0.4 \pm 0.6$  index score points, respectively. The position of the gingival margin at the implant site and the two neighboring teeth remained stable. At the 5-year visit IS-BIC measured between  $1.4 \pm 0.5$  mm (mesial, control) and  $1.7 \pm 0.7$  mm (distal, test), no significant difference could be found between the two groups. Over the observation period no statistically significant change of IS-BIC could be found in the test- as well as in the control-group. None of the examined radiographs revealed any signs of retrograde peri-implantitis. **CONCLUSION:** The replacement of teeth exhibiting periapical pathologies by implants placed immediately after tooth extraction can be a successful treatment modality with no disadvantages in clinical, aesthetical and radiological parameters to immediately placed implants into healthy sockets.

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**A prospective, controlled clinical trial evaluating the clinical radiological and aesthetic outcome after 5 years of immediately placed implants in sockets exhibiting periapical pathology**

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**5 years after immediate implantation into infected sockets**

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**Key words:** bone regeneration, dental implantation, endosseus, human, immediate implant placement, periapical pathology, treatment outcome, aesthetic outcome, controlled clinical trial, prospective study

**Abstract:**

**Objectives:** The aim was to compare the clinical, aesthetic and radiological outcome of immediately placed implants in sockets with or without periapical pathology 5 years after placement.

**Materials and methods:** 27 patients were followed 5 years after immediate implant placement (test-group: 12 patients with periapical pathologies; control-group: 15 patients without periapical pathology). Clinical (FMBS, FMPS, CAL, keratinized mucosa), aesthetical (length of clinical crown, Papilla index) and radiological (vertical distance implant shoulder to first bone to implant contact (IS-BIC)) parameters were assessed. Both 95% confidence intervals, as well as results of statistical tests (one-sample, two-sample, paired t-test) were provided.

**Results:** After 5 years the implant survival rate was 100% for all 27 implants. In the test-group the width of the keratinized mucosa increased significantly over the observation period ( $0.8 \pm 1.0$  mm). Concerning aesthetic parameters at the 3-months as well as at the 5-years examination no statistically significant difference could be found between the two groups. In the control-group the papilla mesial and distal to the implant increased statistically significant during the observation period by  $0.5 \pm 0.5$  and  $0.4 \pm 0.6$  index score points respectively. The position of the gingival margin at the implant site and the two neighboring teeth remained stable. At the 5-years visit IS-BIC measured between  $1.4 \pm 0.5$  mm (mesial, control) and  $1.7 \pm 0.7$  mm (distal, test). No significant difference could be found between the two groups. Over the observation period no statistically significant change of IS-BIC could be found in the test- as well as in the control-group. None of the examined radiographs revealed any signs of retrograde periimplantitis.

**Conclusion:** The replacement of teeth exhibiting periapical pathologies by implants placed immediately after tooth extraction can be a successful treatment modality with no

disadvantages in clinical, aesthetical and radiological parameters to immediately placed implants into healthy sockets.

## **Introduction:**

Immediate implant placement at the time of tooth extraction has been introduced for many years to reduce the amount of surgical interventions and to possibly preserve the pre-extraction contours of the alveolar process (Bragger et al. 1996; Lang et al. 1994; Becker et al. 1994). It has been documented that without concomitant therapies (i.e. bone augmentation or soft tissue augmentation) immediate implants cannot preserve the alveolar ridge dimensions after tooth extraction (Botticelli et al. 2004; Araujo & Lindhe 2005). As a possible consequence of this remodeling process a mean buccal mucosa recession after immediate implantation and provisionalization between 0.5 and 1.5 mm after 6 to 12 months must be anticipated (Evans & Chen 2008; Groisman et al. 2003; Kan et al. 2003; Ryser et al. 2005; Chen et al. 2007). This has led to a general agreement that immediate implants in the esthetic zone are of higher risk for esthetic complications and should, therefore, been used only in selected indications.

An additional factor, which has been discussed controversially in terms of immediate implantation, is the presence or absence of periapical pathologies. There are studies, which advise against immediate placement of implants in the presence of periapical pathologies and others revealed no disadvantages for implants placed directly after extraction of teeth exhibiting periapical pathologies (Tolman & Keller 1991; Barzilay 1993). Furthermore, the term retrograde periimplantitis got recently introduced as radiolucencies around the most apical part of an osseointegrated implant. They might be provoked by remaining scar or granulomatous tissue after immediate implant placement into extraction sockets (Quirynen et al. 2005).

In spite of all these influencing and controversial factors, immediate implant placement remains an interesting therapeutic option for selected indication. It is therefore mandatory to gather more scientific evidence of the long-term aesthetic and clinical outcome of immediate implant placement.

The aim of the present study was to assess whether immediately placed implants in sockets with or without periapical pathology show any differences regarding survival rates, clinical parameters, interproximal bone levels, and aspects concerning the pink aesthetics like gingival recession and volume of the interproximal papilla after 5 years following implant placement. Another purpose was to look for residual or newly formed radiolucencies (retrograde periimplantitis) around the tip of the implants as previously described in the literature.

## **Material and methods:**

### **Study design and patients:**

The present controlled prospective clinical study evaluates patients clinically and radiologically five years after immediate implant placement into extraction sockets of teeth with (test-group) and without periapical pathologies (control-group). All patients had been treated at the Department of fixed and removable prosthodontics and dental material science at the University of Zurich, Switzerland and were in need of tooth replacement with an implant. Implant sites were limited to incisors, canines and premolars. The study population was part of two former studies evaluating the early events and 1-year as well as the 3-years follow-up data (Siegenthaler et al. 2007; Truninger et al. 2011). The local ethical committee approved all procedures and the patients gave or signed informed consent.

The original study included 34 patients, 17 belonging to the test- and control-group each. 29 of them have finally been included in the study and attended the 1-year follow-up visit. Five (4 test- and 1 control-patient) had to be withdrawn as early exits during implant surgery due to inability to obtain primary implant stability. Two of the patients attending the 1-year examination (one of the test- and one of the control-group) couldn't be reached for the 5-years follow-up visit. Therefore, 27 patients attended the 5-years examination. The patients have been included according to the criteria defined in the original publication (Siegenthaler et al. 2007). In brief, 15 out of the 27 patients belonged to the control-group without any signs of periapical pathologies before tooth removal and 12 to the test-group revealing periapical pathologies including pain, periapical radiolucencies >1mm, suppuration or a combination of these findings. The mean age of the patients in the test-group was 53 years (range 31-87 years) whereas that of the control-group was 60 years (range 28-82 years) at the time of the 5-years follow-up visit. All of the patients were in good general health and had no history of periodontal disease. At the 1-year follow-up visit one participant of the test- as well as one of the control-group were smokers. The 5-years follow-up visit was attended by just one

(control-group) of these two smokers whereas the other belonged to the two patients that couldn't been reached for the 5-years visit.

### **Treatment protocol:**

All implants were placed in a similar manner. The surgical procedure has been described in detail in the previous study (Siegenthaler et al. 2007). Briefly, after tooth extraction and thoroughly removing all granulation tissues an implant (Standard Plus or Tapered Effect, Straumann Dental Implant System, Straumann AG, Basel, Switzerland) with dimensions best suited to obtain primary stability was placed immediately in an optimal prosthetic position. In all of the test- and control- procedures guided bone regeneration (GBR) was performed according to standard clinical procedures (Lang et al. 1994; Hammerle et al. 1998) using deproteinized bovine bone mineral **inside and outside of the extraction sockets** (Bio-Oss spongiosa particles, Geistlich-Pharma, Wolhusen, Switzerland) and a resorbable collagen membrane (Bio-Gide, Geistlich-Pharma, Wolhusen, Switzerland). **Subsequently, the implants were left for transmucosal or semisubmerged healing.** For postoperative care the patients received penicillin antibiotics (Amoxicyllin 750 mg 1-1-1) for 5 days and rinsed with a 0.2 % chlorhexidine digluconate solution. After transmucosal or semisubmerged healing, implants were loaded at 3 months after placement. Most of them (22 implants) received single crowns. Two implants in the test-group and one in the control-group were part of an implant supported bridge whereas one implant in each group supported a mixed (implant-tooth supported) bridge. **Per patient only one implant was included in the study.**

### **5-year follow-up data collection:**

#### **Clinical parameters:**

For the clinical assessment after 5 years the following periodontal and periimplant parameters have been recorded:

- Full-mouth bleeding score (FMBS) (Lang et al. 1986)
- Full-mouth plaque score (FMPS) (O'Leary et al. 1972)
- Buccal and oral interproximal clinical attachment level measurements (CAL) at the tooth-sides of the adjacent teeth facing the site of the implant. The mesio-buccal and the mesio-oral as well as the disto-buccal and the disto-oral CAL measurements were averaged to a mesial and a distal value.
- Buccal width of keratinized mucosa (KM) at the site of the implantation.

### **Aesthetical parameters:**

The following aesthetic parameters were assessed by clinical examination and with the help of photographs and study casts taken at the delivery of the implant crowns 3 months after implant placement and at the 5-years follow-up visit:

- Papilla Index score (papilla index mes/dist) according to Jemt mesial and distal to the site of implantation (Jemt 1997) (Fig 1). Index score 0: No papilla is present; Index score 1: Less than half of the height of the papilla is present; Index score 2: At least half of the height of the papilla is present, but not all the way up to the contact point between the clinical crowns; Index score 3: The papilla fills up the entire proximal space and is in good harmony with the adjacent papillae, optimal soft tissue contour; Index score 4: The papilla is hyperplastic and covers too much of the single implant restoration and/or the adjacent tooth. For more detailed information see original publication.
- Axial length of the clinical crown of the implant (CCImpl) and the neighboring teeth mesial (CCmes) and distal (CCdist) to it respectively measured from the zenith of the gingival curvature to the incisal edge or cusp tip.
- Presence or absence of chipping of the veneering ceramic of the implant crown



**Radiological parameters:**

Standardized radiographs taken with the same individual bite blocks as described previously (Siegenthaler et al. 2007) were digitalized and assessed with an image processing program (Image J64, Version 10.2) under a magnification of 10 times. The following parameters have been assessed:

- Vertical bone measurements were taken from the mesial and distal shoulder of the implant to the first bone-to-implant contact level in an axis parallel to the implant (IS-BIC). To adjust each radiograph for distortion the distance between the tips of three threads of the implant was additionally assessed and the vertical measurements were multiplied by the ratio between the manufacturer-specified thread pitch of 0.8 mm (TE Implant), 1.25 mm (Standard Plus Implant, Regular Neck) and 1.0 mm (Standard Plus Implant, Narrow Neck) and the observed distance.
- The periapical area of the implant was observed for possible residual or newly formed periapical radiolucencies.

For both the aesthetic and the radiological parameters two independent examiners performed the measurements. Any disagreements were resolved by discussion aiming for consensus.

**Statistical analysis:**

The statistical analysis based on the power calculation performed in the proceeding study (Truninger et al. 2011) using the implants as the statistical unit. Only one implant per patient was included. A possible bone resorption of 0.2 mm annually was considered clinically relevant after the first year of loading. Consequently, relevant changes between the 1- and 5-year visit should be bigger than 0.4 mm.

One-sample t-test: To detect with 80% power a relevant difference of the primary outcome of  $\Delta = 0.4$  with a standard deviation of  $\sigma = 0.4$ , a sample size of 10 is needed.

Not only the changes in measurements between the 1- and 5-year visit within the test and control group separately were of interest but also the differences of these changes in this 4-year time span between the test and control group were important. Therefore, a difference of 0.5 mm was considered clinically relevant.

Two-sample t-test: To detect with 80% power a relevant difference of the primary outcome of  $\Delta = 0.5$  with a standard deviation of  $\sigma = 0.4$ , a sample size of 11 was needed for each (test and control) group.

The values of descriptive statistics (mean, standard deviation (SD) and median) for IS-BIC mesial/distal, FMBS, FMPS, CAL mesial/distal, width of keratinized mucosa, papilla index mesial/distal and CCmesial/impl/distal were computed at 5 years or 3 months respectively.

The non-parametric Mann-Whitney test was applied to investigate the differences in these parameters between control- and test-group. Additionally, mean and median difference between test- and control-group together with the corresponding 95% confidence interval (95% CI) was given. Changes in IS-BIC mesial/distal, FMBS, FMPS, CAL mesial/distal and the width of keratinized mucosa between 1 and 5 years and changes in papilla index mesial/distal and CCmesial/Impl/distal between 3 months and 5 years were calculated.

Means, standard deviations (SD) and medians were computed. The non-parametric paired Wilcoxon test for control and test group separately was applied. Moreover, the corresponding 95% confidence intervals (95% CI) were provided. The non-parametric Mann-Whitney test was applied in order to disclose differences in changes of IS-BIC mesial/distal, FMBS, FMPS, CAL mesial/distal width of keratinized mucosa, papilla index mesial/distal and CCmesial/Impl/distal between test- and control-group. Mean and median differences between groups together with the corresponding 95% confidence intervals were provided. Results of the tests with p-values less than 5% were considered to be statistically significant.

## **Results:**

27 out of 29 patients attending the 1-year visit could be recruited for the 5-year follow-up visit (12 in the test group and 15 in the control group). The implant survival rate was 100% with 95% CI (87%, 100%) for all 27 implants after 5 years. For a pessimistic estimate of survival where drop-outs were treated as potentially failed the survival would be 93% with 95% CI (77%, 99%).

Two patients, one of the control- and one of the test-group refused to take X-ray pictures at the 5-year follow-up visit, rendering 11 patients in the test- and 14 patients in the control-group for radiographic evaluation.

### **Clinical measurements at 5 years (test: n=12; control: n=15)**

The clinical measurements at the 5-years follow-up visit are displayed in Table 1. Regarding the statistical analysis none of the parameters except for full mouth bleeding score (FMBS) revealed a statistical significant difference between the two groups at 5 years. The differences of the clinical measurements between 5 and 1 years are displayed in Table 2. The statistical analysis of the test-group revealed a significant increase of the width of the keratinized mucosa buccally of the site of implantation. In the control-group the FMBS significantly decreased and the clinical attachment level at the tooth-side mesial of the implant significantly **decreased** between the two evaluation time-points. When comparing the differences between the 5- and the 1-year evaluation of the test- and the control-group with each other, the changes of the FMBS **as well as dCal mesial** in the two groups were significantly different. All other clinical measurements showed no significant difference between the test-and control-group.

### **Aesthetic measurements at 3 months and at 5 years (test: n=12; control: n=15)**

The aesthetic measurements at the 3 months, - i.e. crown insertion - as well as at the 5-years follow-up visit are displayed in Tables 3 and 4. Regarding the statistical analysis none of the parameters revealed any statistical significant difference between the two groups neither at the 3-months nor at 5-years visit.

The comparison of the esthetic measurements between 3 months and 5 years revealed stable soft tissue values with no facial recession neither at the implant sites nor at the neighboring teeth (Table 5). The corresponding values for change of the axial height of the clinical crown ranged between 0.1 mm (dCCImpl) and 0.2 mm (dCCmes/dist) for the test- and -0.1 mm (dCCImpl/dist) and 0.0 mm (dCCmes) for the control-group respectively. No statistical significant difference could be found neither within the groups nor when comparing the two groups. The Papilla index mesial and distal to the implants increased in both the test- and the control-group. The corresponding values ranged between 0.3 (dPapilla index mes/dist, test-group) and 0.5 (dPapilla index mes, control-group). Only for the control-group this increase of the Papilla index mesial and distal to the implant reached statistical significance. No statistical significant difference could be found when comparing the two groups. None of the examined implant crowns showed any sign of fractures or chipping of the veneering ceramic.

### **Radiological measurements at 5 years (test: n=11; control: n=14)**

The vertical distance from the implant shoulder to the first bone-to-implant contact mesial of the implant site was  $1.5 \pm 0.8$  mm in the test-group (range from 0.7 to 3.1 mm) and  $1.4 \pm 0.5$  mm in the control-group (range from 0.6 to 2.1 mm) (Table 6). On the distal aspect of the implant, the values were  $1.7 \pm 0.7$  mm in the test-group (range from 0.7 to 3.3 mm) and  $1.5 \pm 0.6$  mm in the control-group (range from 0.8 to 2.9 mm). There was no statistically significant difference between the groups at 5 years. The differences of the radiological measurements between 5 and 1 years are shown in Table 7. Within the test- and control-group

there was no statistically significant change in the vertical distance measured from implant shoulder to the first bone-to-implant contact (IS-BIC) on the mesial or the distal side of the implant. Also when comparing the bone level changes between the 5- and the 1-year evaluation of the test- and the control-group with each other, there was no statistically significant difference. After 5 years none of the 25 examined radiographs revealed radiolucencies around the tip of the implants neither in the control- nor in the test-group (Fig. 2 and 3).

## **Discussion:**

The results of the present study have demonstrated that immediate placement of implants into extraction sockets of teeth with periapical pathologies doesn't lead to any radiological, clinical or aesthetical differences compared to implants immediately placed into sockets of teeth without periapical pathologies. After the observation period of 5 years there was no statistical significant difference regarding the survival rate between the two groups. Five years after immediate implant placement the radiological evaluation revealed no statistically significant differences between the test- and control-group. There was no significant change of the position of first bone to implant contact within the two groups between the one- and five-years examinations. The mean change measured between -0.3 mm (test-group distal) and 0.2 mm (control-group distal, test-group mesial). In the former study, evaluating the changes between implant placement and 1 year, a bone loss of up to 1.9 mm measured between the alveolar crest of the tooth to be extracted and the first bone to implant contact was reported (Siegenthaler et al. 2007). It can therefore be concluded, that marginal bone loss takes mainly place within the first 12 months after implant placement. This phase of initial bone loss seems to be followed by a phase of stability in which the marginal bone level doesn't change substantially any more. This is in accordance to other studies on this topic. A

prospective clinical study with 76 participants who were followed up to two years could show that bone loss took exclusively place within the first 6 months after immediate or delayed implant placement (Block et al. 2009). In the present study the observed bone loss of  $\leq 0.2$  mm between 1 and 5 years seems to be remarkably low compared to other publications. A 5-year prospective clinical study with 55 participants measured an annual bone loss of 0.2 mm after early and delayed implant placement (Schropp & Isidor 2008). Similar values have been published in other studies (Albrektsson et al. 1986; Schropp et al. 2005; Buser et al. 2009; Juodzbaly & Wang 2007). The low bone loss values found in the present study are difficult to be explained. It can be speculated that it is due to the fact that the present patients were well maintained (low FMBS and FMPS) throughout the 5 years observation period. In addition, it has to be taken into consideration that the majority of the bone level changes happened within the first year after implant placement, which has already been extensively discussed in the former publication (Siegenthaler et al. 2007). As reported in the previous studies no radiolucencies could be found around the apex of any implant neither in the test- nor in the control-group 5 years after implant placement (Siegenthaler et al. 2007; Truninger et al. 2011). This is in agreement with other reports on this topic (Quirynen et al. 2005; Casap et al. 2007).

The implant survival rate in this study was 100%. This is in agreement with previous publications demonstrating similar survival rates of implants placed immediately after tooth extraction with the use of GBR procedures. Most of these studies report survival rates of over 95% over the first 1 to 5 years after implant insertion. (Juodzbaly & Wang 2007; Chen & Buser 2009; Lang et al. 1994; Becker et al. 1994; Rosenquist & Ahmed 2000; Hammerle & Lang 2001; Nemcovsky et al. 2002; Bianchi & Sanfilippo 2004; Schropp & Isidor 2008)

The esthetic evaluation of the implant reconstruction has only been performed within the present paper and not within the more recent studies (Siegenthaler et al. 2007; Truninger et al. 2011). A commonly used index is the Papilla Index of Jemt (Jemt 1997). During the

observation period the papilla mesial and distal to the implant improved in both the test- and the control group. However, only for the control-group this improvement reached statistical significance. This implies that the present technique was able to maintain or even improve the papillae height and appearance after delivery of the crown. This is in accordance to other publications made on this topic. A retrospective clinical study including 25 implant supported single crowns in 21 patients showed an increase of the papilla index score mesial and distal to the crown of around one score point in the first 1.5 years after implant loading (Jemt 1997; Jemt & Lekholm 2003). Many other studies with follow-ups of up to 5-years showed similar findings, i.e. significant soft tissue fill in the proximal spaces, (Jemt & Lekholm 2003; Cardaropoli et al. 2006; Schropp & Isidor 2008; Romeo et al. 2008). The mean papilla index observed in this study was in the order of magnitude of other studies made on this topic (Juodzbaly & Wang 2007).

During the observation period the axial height of the clinical crowns of the implant and the two neighboring teeth didn't change. In other words, no recession occurred neither in the test- nor in the control-group. A review of the current literature revealed that recession of the facial mucosal margin is common with immediate implant placement. (Chen & Buser 2009). Risk indicators included a thin tissue biotype, a facial malposition of the implant and a thin or damaged facial bone wall (Evans & Chen 2008; Chen et al. 2007). In the present study all these factors have been carefully taken in to consideration preoperatively as well as during extraction and implant placement. Care was taken to position the implant sufficiently palatal/lingual in order to have a distance to the facial bone wall of at least 2 mm. In addition, all sites were grafted to the buccal side using DBBM and a collagen membrane and were not immediately restored. This might help to predictably better maintain the buccal mucosal margin after immediate implant placement and subsequent prosthetic reconstruction.

The stable mucosa margin is also documented by the finding, that the width of the keratinized mucosa buccal to the implant increased in both groups over the observation period but only

for the test-group the difference was statistically significant. Whether or not there is a need of keratinized mucosa around dental implants has been widely and controversially discussed in the past. However, recent publications could show that a narrow zone of peri-implant keratinized mucosa (< 2mm) results in higher Gingival index score, Plaque index score, Bleeding on probing, mucosal recession and marginal bone resorption at the implant site (Kim et al. 2009; Crespi et al. 2010; Schrott et al. 2009; Bouri et al. 2008). Due to a well-established maintenance program for the present patients, the clinical parameters (i.e. FMBS; FMPS) stayed stable and remarkably low over the observed 5 years. This might also explain the very stable mucosa margin over the time.

Regarding the prosthetic evaluation none of the examined implant crowns showed any sign of fractures or chipping of the veneering ceramic. A former systematic review including 26 studies assessed the survival rate of 1558 implant supported single crowns over 5 years. 4.5% of the crowns showed some kind of fracture or chipping of the veneering material and 3% of the crown framework, respectively (Jung et al. 2008).

It can be concluded, that replacement of teeth exhibiting periapical pathologies by implants placed immediately after tooth extraction can be a successful treatment modality with no disadvantages in clinical, aesthetical and radiological parameters to immediately placed implants into healthy sockets. It can further be concluded that immediate implant placement following the present preoperative and operative procedures leads to very stable clinical, radiological and aesthetic outcomes with minimal changes over a 5 year observation period.





Table 1. Clinical measurements excluding early exit cases and drop-outs at 5 years

	Mean(SD); <i>Median</i>		Difference between control- and test-group	
Clinical measurements	Test, n= 12	Control, n=15	Mean difference (95% CI); <i>Median</i>	p-value
FMBS (%)	18.5(11.2); <i>12.0</i>	9.9(5.1); <i>9.0</i>	-8.6(-16.0,-1.1); <i>-3.0</i>	<i>0.012*</i>
FMPS (%)	22.9(15.7); <i>20.5</i>	17.5(12.8); <i>14.0</i>	-5.4(-16.7,5.9); <i>-6.5</i>	<i>0.323</i>
CAL mesial (mm)	2.8(1.0); <i>3.0</i>	3.5(1.2); <i>3.0</i>	0.7(-0.2,1.6); <i>0.0</i>	<i>0.193</i>
CAL distal (mm)	2.7(0.9); <i>2.5</i>	3.3(1.1); <i>3.0</i>	0.6(-0.3,1.5); <i>0.5</i>	<i>0.284</i>
KM site (mm)	3.7(1.2); <i>3.5</i>	3.3(1.5); <i>3.0</i>	-0.4(-1.5,0.7); <i>-0.5</i>	<i>0.399</i>
FMBS: full-mouth bleeding score; FMPS: full-mouth plaque score; CAL mesial/distal: interproximal clinical attachment level at the tooth-sides of the adjacent teeth facing the site of the implantation, the buccal and oral values were averaged to one value; KM site: width of keratinized mucosa buccaly of the site of implantation; p-value: <i>Mann-Whitney</i> test; *: statistically significant difference <0.05; SD: standard deviation; 95% CI: 95% Confidence Interval.				

Table 2. Differences of clinical measurements between 5 and 1 years

	Mean(SD) and median difference within groups between 5 and 1 years						Difference between control- and test-group		
	Test, n= 12			Control, n=15					
	Mean(SD); Median	95% CI	p-value†	Mean(SD); Median	95% CI	p-value†	Mean; Median	95% CI	p-value††
dFMBS (%)	5.8(12.0); 5.0	(-1.9,13.4)	0.182	-5.4 (6.0) ); -5.0	(-8.7,-2.1)	0.005*	-11.2; -10.0	(-19.2,-3.1)	0.012*
dFMPS (%)	2.8(19.0); -0.5	(-9.2,14.9)	0.875	-3.8 (16.2) ); -7.0	(-12.8,5.2)	0.280	-6.6; -6.5	(-20.6,7.3)	0.236
dCAL mesial (mm)	-0.3(1.3); -0.5	(-1.1,0.6)	0.465	0.6 (0.9) ); 0.5	(0.1,1.2)	0.031*	0.9; 1.0	(-0.03,1.8)	0.041*
dCAL distal (mm)	-0.4(1.2); -0.5	(-1.2,0.5)	0.281	-0.1 (1.1) ); 0.0	(-0.7,0.6)	0.944	0.3; 0.5	(-0.7,1.2)	0.410
dKM site (mm)	0.8(1.0); 1.0	(0.1,1.4)	0.021*	0.4 (0.9) ); 0.0	(-0.1,0.9)	0.107	-0.4; -1.0	(-1.1,0.4)	0.347
† Wilcoxon-test; †† Mann-Whitney-test; 95% CI: 95% Confidence Interval; *: statistically significant difference <0.05; SD: standard deviation All differences were calculated 5-years-values minus 1-year-values. To calculate the differences between control- and test-group, control- minus test-group values were computed. dFMBS: difference in full-mouth bleeding score between 5 and 1 years; dFMPS: difference in full-mouth plaque score between 5 and 1 years; dCAL mesial/distal: difference in interproximal clinical attachment level at the tooth-sides of the adjacent teeth facing the site of the implantation between 5 and 1 years, the buccal and oral values were averaged to one value. A positive value represents a loss of CAL, a negative value a CAL gain; dKM site: difference in width of keratinized mucosa buccaly of the site of implantation between 5 and 1 years.									

Table 3. Aesthetic measurements excluding early exit cases and drop-outs at 3 months

	Mean(SD); <i>Median</i>		Difference between control- and test-group	
	Test, n= 12	Control, n=15	Mean difference, (95% CI); <i>Median</i>	p-value
Aesthetic measurements at 3 months				
CCmes (mm)	9.9(1.5); <i>9.6</i>	9.8(1.4); <i>9.7</i>	-0.1(-1.3,1.1); <i>0.1</i>	<i>0.685</i>
CCImpl (mm)	9.7(2.2); <i>9.4</i>	9.2(1.7); <i>9.3</i>	-0.5(-2.0,1.0); <i>-0.1</i>	<i>0.685</i>
CCdist (mm)	9.3(1.4); <i>9.4</i>	8.6(1.5); <i>9.2</i>	-0.6(-1.8,0.5); <i>-0.2</i>	<i>0.375</i>
Papilla index mesial	1.7(0.7); <i>2.0</i>	2.1(0.8); <i>2.0</i>	0.4(-0.2,1.0); <i>0.0</i>	<i>0.274</i>
Papilla index distal	1.3(1.1); <i>1.0</i>	1.7(0.9); <i>2.0</i>	0.5(-0.4,1.3); <i>1.0</i>	<i>0.297</i>
CCmes: Axial height of the clinical crown mesial to the implant crown; CCImpl: Axial height of the clinical implant crown; CCdist: Axial height of the clinical crown distal to the implant crown; Papilla index mesial/distal: Papilla index according to Jemt mesial/distal to the implant crown; p-value: <i>Mann-Whitney</i> -test; *: statistically significant difference <0.05; SD: standard deviation; CI: 95% Confidence Interval.				

Table 4. Aesthetic measurements excluding early exit cases and drop-outs at 5 years

	Mean(SD); <i>Median</i>		Difference between control- and test-group	
	Test, n= 12	Control, n=15	Mean difference (95% CI); <i>Median</i>	p-value
Aesthetic measurements at 5 years				
CCmes (mm)	10.0(1.3); <i>10.0</i>	9.8(1.6) ; <i>9.9</i>	-0.2(-1.4,1.0); <i>-0.1</i>	<i>0.781</i>
CCImpl (mm)	9.7(2.3); <i>9.1</i>	9.1(1.9) ; <i>9.4</i>	-0.6(-2.3,1.1); <i>0.3</i>	<i>0.742</i>
CCdist (mm)	9.2(1.2); <i>9.1</i>	8.6(2.0) ; <i>9.2</i>	-0.7(-2.0,0.7); <i>0.1</i>	<i>0.705</i>
Papilla index mesial	2.0(1.1); <i>2.0</i>	2.6(0.6) ; <i>3.0</i>	0.6(-0.2,1.3); <i>1.0</i>	<i>0.231</i>
Papilla index distal	1.6(1.1); <i>2.0</i>	2.1(0.8) ; <i>3.0</i>	0.6(-0.2,1.3); <i>1.0</i>	<i>0.231</i>
CCmes: Axial height of the clinical crown mesial to the implant crown; CCImpl: Axial height of the clinical implant crown; CCdist: Axial height of the clinical crown distal to the implant crown; Papilla index mesial/distal: Papilla index according to Jemt mesial/distal to the implant crown; p-value: <i>Mann-Whitney-test</i> ; *: statistically significant difference <0.05; SD: standard deviation; CI: 95% Confidence Interval.				

Table 5. Differences of aesthetic measurements between 5 years and 3 months

	Mean(SD) and median difference within groups between 5 years and 3 months						Difference between control- and test-group		
	Test, n= 12			Control, n=15					
	Mean(SD); Median	95% CI	p-value†	Mean(SD); Median	95% CI	p-value†	Mean; Median	95% CI	p-value††
dCCmes (mm)	0.2(0.5); 0.2	(-0.1,0.5)	0.279	-0.0(0.4); -0.1	(-0.3,0.2)	0.975	-0.2; -0.3	(-0.6,0.1)	0.527
dCCImpl (mm)	0.1(0.3); 0.1	(-0.2,0.3)	0.472	-0.1(0.7); -0.1	(-0.5,0.3)	0.396	-0.2; -0.2	(-0.7,0.3)	0.252
dCCdist (mm)	0.2(0.4); 0.2	(-0.1,0.4)	0.283	-0.1(0.8); 0.1	(-0.5,0.4)	0.400	-0.2; -0.1	(-0.7,0.3)	0.560
dPapilla index mes	0.3(0.8); 0.5	(-0.2,0.8)	0.157	0.5(0.5); 0.5	(0.2,0.8)	0.008*	0.2; 0.0	(-0.4,0.7)	0.742
dPapilla index dist	0.3(0.8); 0.0	(-0.2,0.8)	0.157	0.4(0.6); 0.0	(0.1,0.8)	0.034*	0.1; 0.0	(-0.5,0.7)	0.781
† Wilcoxon-test; †† Mann-Whitney-test; 95% CI: 95% Confidence interval; *: statistically significant difference <0.05; SD: standard deviation All differences were calculated 5-years-values minus 3-months-values. To calculate the differences between test- and control-group, control- minus test-group-values were computed. dCCmes/Impl/dist: difference in axial height of the clinical crown of the implant and the neighbouring teeth mesial/distal to it respectively between 3 months and 5 years. A positive value represents a recession of the gingival margin. dPapilla index mes/dist: difference in Papilla index according to Jemt mesial/distal to the implant crown between 3 months and 5 years. A positive value represents a soft tissue fill.									

Table 6. Radiological measurements excluding early exit cases and drop-outs at 5 years

Radiological measurements	Mean(SD); <i>Median</i>		Difference between control- and test-group	
	Test, n= 11	Control, n=14	Mean difference (95% CI)	p-value
IS-BIC mesial (mm)	1.5(0.8); <i>1.1</i>	1.4(0.5); <i>1.4</i>	-0.1(-0.7,0.5); <i>0.3</i>	<i>0.936</i>
IS-BIC distal (mm)	1.7(0.7); <i>1.6</i>	1.5(0.6); <i>1.5</i>	-0.2(-0.8,0.4); <i>-0.1</i>	<i>0.536</i>
IS-BIC mesial/distal: vertical distance from the implant shoulder to the first bone-to-implant contact on the mesial or distal side; p-value: <i>Mann-Whitney-test</i> ; *: statistically significant difference <0.05; SD: standard deviation; CI: 95% Confidence Interval.				

Table 7. Differences of radiological measurements between 5 and 1 years

	Mean(SD) and <i>median</i> difference within groups between 5 and 1 years						Difference between control- and test-group		
	Test, n= 11			Control, n=14					
	Mean(SD); <i>Median</i>	95% CI	p-value†	Mean(SD); <i>Median</i>	95% CI	p-value††	Mean; <i>Median</i>	95% CI	p-value††
Change IS-BIC mesial (mm)	0.2(0.4); <i>0.3</i>	(-0.1,0.4)	<i>0.155</i>	-0.1(0.4); <i>-0.6</i>	(-0.3,0.1)	<i>0.300</i>	-0.3; <i>-0.9</i>	(-0.6,0.04)	<i>0.058</i>
Change IS-BIC distal (mm)	-0.3(0.7); <i>0.0</i>	(-0.8,0.2)	<i>0.477</i>	0.2(0.6); <i>0.3</i>	(-0.2,0.5)	<i>0.109</i>	0.5; <i>0.3</i>	(-0.1, 1.1)	<i>0.051</i>
† <i>Wilcoxon-test</i> ; †† <i>Mann-Whitney-test</i> ; 95% CI: 95% Confidence interval; *: statistically significant difference <0.05; SD: standard deviation All differences were calculated 5-year-values minus 1-year-values. To calculate the differences between test- and control-group, control- minus test-group-values were computed. Change IS-BIC mesial/distal: change of vertical distance from the implant shoulder to the first bone-to-implant contact mesial/distal from the 5- to the 1-year visit. A positive value represents a bone loss, a negative value a bone gain.									



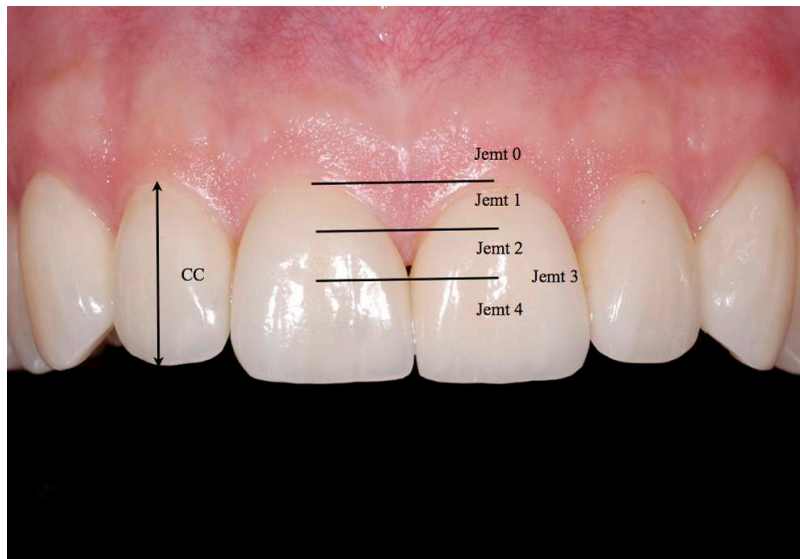


Fig. 1: Measurement of aesthetic parameters. CC: Axial length of clinical crown measured from the zenith of the gingival curvature to the incisal edge or cusp tip. Papilla index score according to Jemt (Jemt 1997).

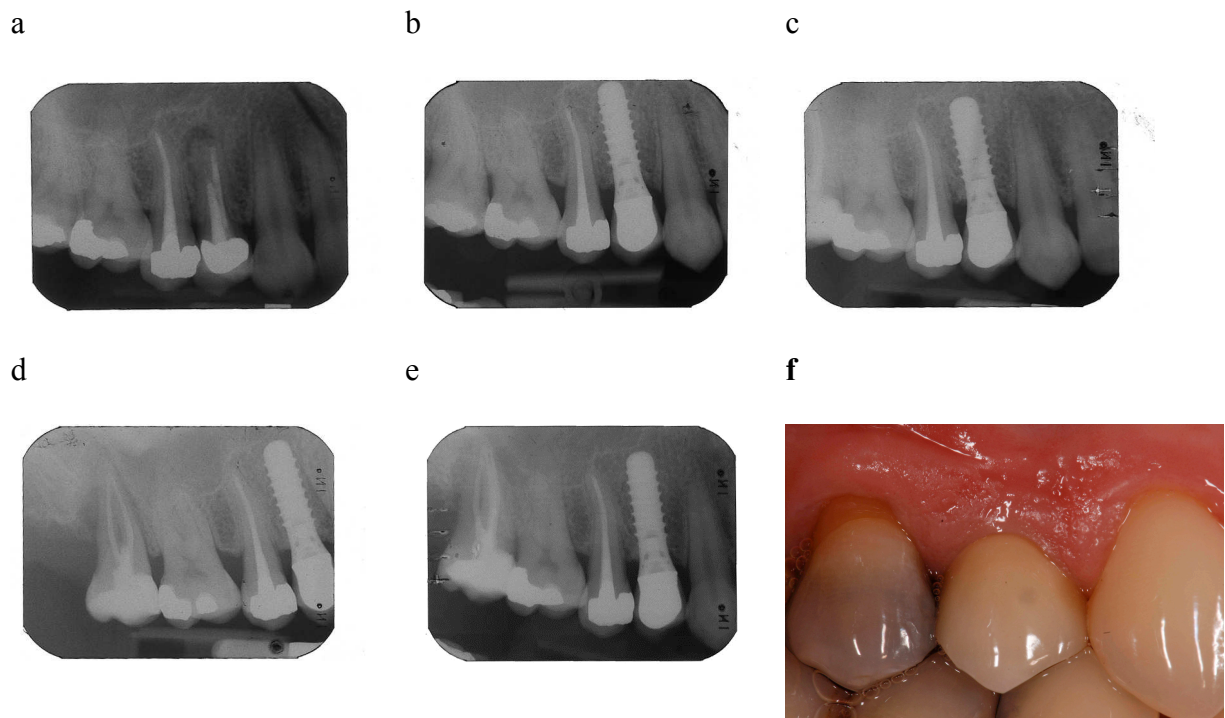


Fig. 2: Periapical radiographs showing a test implant at position 14. a: at baseline, b: at loading after 3 months, c: at 1 year after placement, d: at 3 years after placement, e: at 5 years after placement, f: clinical photograph of crown 14 at 5 years after placement

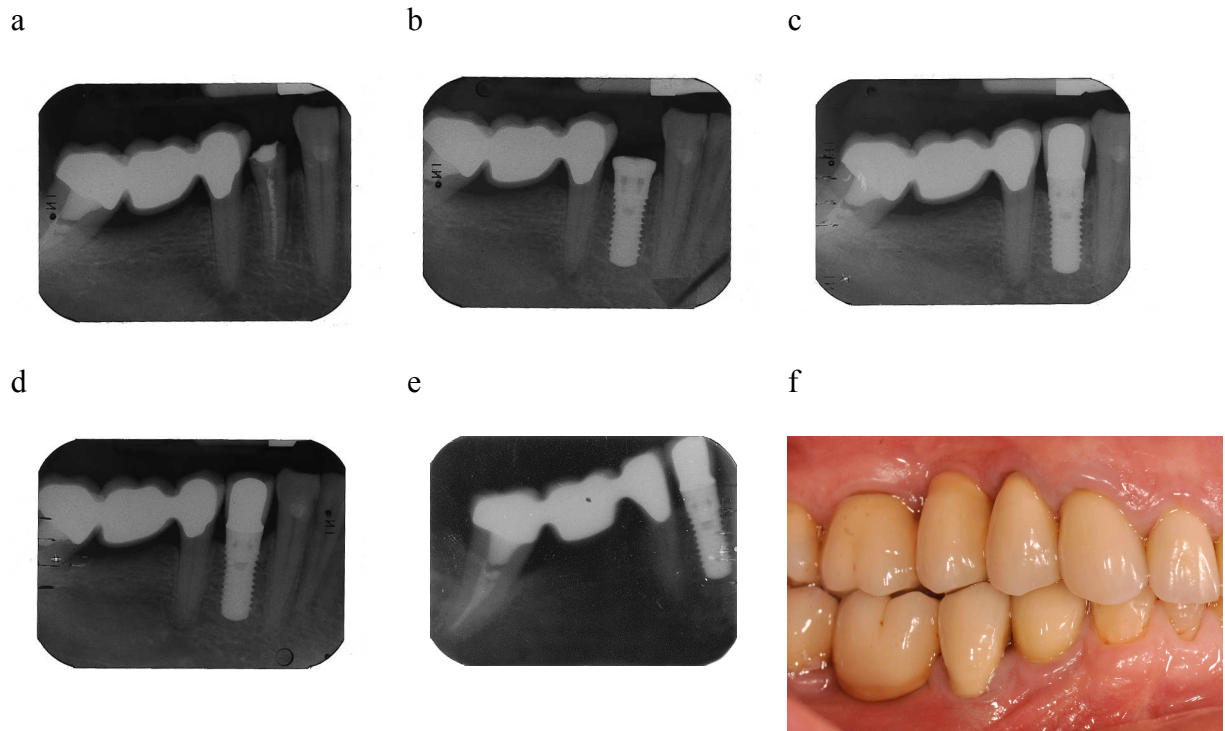


Fig. 3: Periapical radiographs showing a control implant at position 44. a: at baseline, b: at loading after 3 months, c: at 1 year after placement, d: at 3 years after placement, e: at 5 years after placement, f: clinical photograph of crown 44 at 5 years after placement

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